

K173201 UNITY Sacroiliac Joint Fixation SystemApr 26, 2018
206 days to decisionK173201 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k173201/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Oct 2, 2017
Decision date	Apr 26, 2018
Days to decision	206 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Huvexel Co. , Ltd.
Location	Seongnam-Si, KR
Contact	Sung Hee-Lee
510(k) history	8 submissions · 8 cleared · 2017-2022

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